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In the Supreme Court of the United States

OCTOBER TERM, 1978

RAY MARSHALL, SECRETARY OF LABOR

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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The Solicitor General, on behalf of the Secretary of Labor,[1] petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-33a)[2] is reported at 581 F.2d 493. The regulation in ques-

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[1] The petitions for review of the regulation in the court of appeals named the Occupational Safety and Health Administration as the federal party. Because the Secretary of Labor is ultimately responsible for the promulgation and enforcement of the regulation, we have named him as petitioner here.

[2] "App." refers to the separately bound appendix to the petition in No. 78-911, which seeks review of the same judgment. Because we believe that the Court should grant review in No. 78-911, which presents essentially the same questions as the present petition, we will not file a separate response in that case.

tion and the administrative opinion (App. 34a-252a) appear at 43 Fed. Reg. 5918-5970.

JURISDICTION

The judgment of the court of appeals (App. 254a-255a) was entered on October 5, 1978. The jurisdiction of this Court is invoked under 28 U.S.C. 1254 (1).

QUESTIONS PRESENTED

1. Whether a health and safety standard for a toxic substance promulgated by the Secretary of Labor pursuant to 29 U.S.C. 655(b) must satisfy a cost-benefit test.

2. Whether a health and safety standard that is supported by substantial evidence based on the best available scientific knowledge may be set aside because of the possibility that future scientific studies will provide better evidence concerning the need for the standard.

STATUTE INVOLVED

Section 6(b)(5) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 655(b)(5), provides:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period

> of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

Section 3(8) of the Act, 29 U.S.C. 652(8), provides:

> The term "occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

STATEMENT

1. The Occupational Safety and Health Act of 1970 (OSHA), 29 U.S.C. 651 *et seq.*, was enacted "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. 651. See *Atlas Roofing Co.* v. *OSHRC*, 430 U.S. 442, 444-445 (1977). The Act directs the Secretary of Labor to set occupational safety and health standards to achieve this objective. 29 U.S.C. 655. The Secretary has determined that benzene poses a serious health hazard to employees who are exposed

to it, and he has issued three standards regulating the exposure of employees to benzene.[3]

During the first two years of OSHA's existence, the Secretary was required to adopt as his regulation any "national consensus standard" or "established Federal standard," unless he determined that the promulgation of such a standard would not result in improved health or safety. 29 U.S.C. 655(a). In 1971 the Secretary adopted an existing "national consensus standard" establishing limits on occupational exposure to benzene. The 1971 standard provided that average exposure over an eight-hour period could not exceed 10 parts of benzene per million parts of air (ppm), and that short-term exposure could not exceed 50 ppm (App. 71a). The 1971 standard was designed to control the long-recognized toxic non-malignant effects of benzene. The Secretary later received scientific evidence, including a report of the National Institute for Occupational Safety and Health, that benzene posed a risk of leukemia. On May 3, 1977, the Secretary issued an emergency temporary standard for benzene (see 29 U.S.C. 655(c)). Because of a temporary restraining order, the emergency standard never became effective (App. 73a-74a).

This case involves the Secretary's third benzene standard, which was promulgated after full rulemaking addressed to the leukemia hazard. The Secretary

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[3] Benzene, a highly volatile liquid, is a hydrocarbon with many industrial uses. Only 11 other chemicals are produced in greater tonnage in the United States. Production of benzene has been increasing rapidly (App. 69a).

published a proposed permanent benzene standard on May 27, 1977. Public hearings were held; 95 witnesses, representing employers and employees from the petroleum refining, petrochemical, oil and gas production, aviation fueling, coke oven and coke by-products industries, gave testimony (App. 74a). Comments were received from other industries, public interest groups and government agencies (*ibid.*). Briefs, arguments and additional evidence were submitted (*id.* at 75a).

The final benzene standard reduces the permissible exposure level to an average of one ppm over an eight-hour day and reduces the limit for any 15-minute period to five ppm. It prohibits dermal and eye contact with certain liquids containing benzene, and it requires employers to monitor and enforce the exposure levels.[4]

The Secretary published a lengthy statement of reasons for adopting the rule (App. 67a-251a). The Secretary described evidence showing that benzene

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[4] Although the standard initially prohibited dermal and eye contact with any liquid containing any benzene, the standard was amended on June 27, 1978, to exempt all liquids containing 0.5% or less benzene by volume for an interim period of three years, after which the exemption covers all liquids containing 0.1% or less benzene by volume (App. 252a). The standard also requires employers to assure that caution labels are affixed to containers of products containing benzene and requires such labels to remain affixed when the products leave the workplace (App. 47a-48a). The standard requires respiratory protection in limited situations (App. 40a), medical surveillance (App. 42a-46a), employee training programs (App. 46a-47a), and retention of records regarding medical surveillance and exposure monitoring (App. 48a-51a).

causes leukemia and non-malignant diseases as well. Blood disorders induced by benzene have caused deaths (App. 84a-89a); some studies reported blood abnormalities at levels below 25 ppm, perhaps as low as 10 ppm (*id.* at 97a). Observing that "prudent public health policy, and established toxicological principles necessitates setting the permissible exposure limit sufficiently below the levels at which adverse effects have been observed to assure adequate protection," and that "[i]t is customary to use a safety factor of 10-100 or greater depending on the seriousness of the toxic effects and the nature of the data being relied upon," the Secretary stated that a permissible exposure limit "substantially less than 10 ppm without regard to the issue of leukemia" would be warranted (App. 97a-98a).

Although the evidence that benzene causes leukemia was basically uncontroverted (App. 122a), industry representatives presented several "negative studies"—studies of purportedly exposed workers who did not contract leukemia—in an attempt to demonstrate that there was a threshold of exposure (higher than 10 ppm) below which there was no risk of leukemia. The Secretary concluded that these studies were unpersuasive, both because epidemiological studies are imprecise and because these studies, in particular, had serious deficiencies.[5] The majority of the cancer specialists appearing at the hearing testified that there

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[5] Several of the studies, for example, did not separate workers who were not exposed to benzene from those who were exposed in computing risks from exposure (App. 124a-125a).

was no known safe level of exposure to benzene (App. 182a-187a; Tr. 351-363, 775-780, 1053). This testimony was consistent with the 1970 report of the National Cancer Institute's Ad Hoc Committee on the Evaluation of Low Levels of Environmental Carcinogens.

The Secretary thus concluded that the evidence established no known safe level for exposure to benzene (App. 124a-125a). He explained that "once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk" (App. 124a, 132a, 160a, 185-186a). The evidence, including a study of the technology required to reduce the level and the expense to do so, demonstrated that the one ppm standard with a ceiling of five ppm was the lowest feasible level, and the Secretary therefore adopted it (App. 132a-135a, 185a-187a).[6]

The Secretary also concluded that a health risk was posed by dermal or eye contact with liquids containing more than 0.5% benzene by volume (see note 4, *supra*). The evidence revealed a scientific consensus—based on test data, benzene's physical characteristics, and experience with similar chemicals—that absorption through skin is a potential source of exposure. In accordance with the agency's policy

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[6] The Secretary estimated that the new standard would increase operating costs for all industries during the first year by between $187 million and $205 million; that the rule would require recurring annual expenditures of approximately $34 million; and that necessary investment in engineering controls would be approximately $266 million (App. 134a).

that, "in dealing with a carcinogen, all potential routes of exposure (i.e. inhalation, ingestion, and skin absorption) should be limited to the extent feasible" (App. 192a), the Secretary therefore required the use of inexpensive impermeable clothing to prevent skin and eye contact (App. 193a-194a).

The Secretary rejected the argument that a rule about toxic substances must be justified by an attempt to assess the benefits of improved health and to weigh those benefits against the cost of the regulation and the costs of other "socially acceptable risks" (App. 158a-163a). The Secretary pointed out that the evidence did not permit the drawing of conclusions about the exact relationship between decreasing levels of exposure and disease; unless it could be learned exactly how much disease could be avoided by each one ppm decrease in exposure, it would be impossible to know the benefits of the particular proposed regulation. The most that could be said with confidence, the Secretary concluded, is that decreased exposure would lead to reduced risk, and thus save lives. The reduction to one ppm exposure is likely, said the Secretary, to carry with it "appreciable" health benefits. The Secretary believed that the statute and the state of scientific knowledge together required adoption of the lowest feasible level for carcinogenic materials, at least so long as there is no known safe level. Only this position, the Secretary stated, could yield "the" standard that "most adequately assures, to the extent feasible" that "no" employee would suffer health impairment as a result of employment, as Section 655 (b)(5) requires (App. 159a-162a).

2. The court of appeals concluded that substantial evidence supports the Secretary's findings that (1) benzene causes cancer (App. 18a); (2) benzene causes diseases (some of them fatal) other than cancer (App. 7a); (3) exposure at the 10 ppm level poses a leukemia risk, and exposure at the one ppm level poses less leukemia risk (App. 18a). The court acknowledged that it is not now possible to determine the exact relationship between exposure and risk (App. 19a n.23); it did not dispute the Secretary's finding that the one ppm standard is economically and technologically feasible.

The court nevertheless set aside the standard. It concluded that the Secretary must demonstrate that the lower exposure level saves enough lives that the saving bears a "reasonable relationship" to the cost of implementing the standard (App. 19a-20a). This statutory requirement, the court held, had not been met, principally because the Secretary did not calculate the precise relationship between exposure and risk. The court found the requirement that the Secretary establish a "reasonable" relationship between known costs and known benefits in the section of the Act that defines a health standard as a rule "reasonably necessary or appropriate" to protect health (29 U.S.C. 652(8)). A standard could not be "reasonably necessary," the court concluded, unless it produced known benefits or savings commensurate with its known costs.

Recognizing that OSHA calls for the "highest degree of health and safety protection" and establishes

that the Secretary must adopt for toxic materials the standard that "most adequately assures, to the extent feasible" health protection (29 U.S.C. 655(b)(5)), the court stated that the Secretary does not have "unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost" (App. 15a). The court pointed out that Section 655(b)(5) also requires the standards to be "feasible" and instructs the Secretary to consider "the best available evidence * * * research, demonstrations, experiments." These provisions suggested to the court that the statute contains "pragmatic limitations" (App. 16a), including a requirement to strike a balance between known costs and known benefits.[7]

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[7] The Secretary argued that the standard could satisfy a cost-benefit test, if one were required. The court rejected this argument because, although the cost was not in dispute, the benefits were not well known. Conceding that "some" health benefits would result from the lower standard, the court held that there is no substantial evidence to support the Secretary's finding that the benefits may well be "appreciable" (App. 18a-19a). The court predicted that "valid extrapolations will be possible as more is known about the effects of past exposure at higher levels" (App. 19a n.23). The court stated that when "studies of the effects of human exposure to benzene at higher concentration levels in the past are sufficient to enable a dose-response curve to be charted that can reasonably be projected to the lower exposure levels, or when studies of the effects of animal exposure to benzene are sufficient to make projections of the risks involved with exposure at low levels, then OSHA will be able to make rough but educated estimates of the extent of benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm. Until such estimates are possible, OSHA does not have suffi-

The court also invalidated the prohibition on dermal contact with liquids containing benzene. The Secretary had considered conflicting medical opinions on the question whether benzene could be absorbed through the skin and thereby pose a risk of disease. Although the court acknowledged that the Secretary's finding that dermal contact with benzene poses a cancer risk is supported by substantial evidence (App. 25a), the court noted that one physician had testified that an experiment using radioactive benzene could be conducted to determine conclusively whether benzene is absorbed through the skin. No such experiment had been conducted, but the testimony led the court to hold that the Secretary may not proceed in the absence of such "readily" available evidence, because the rules must be based on the "best available evidence." 29 U.S.C. 655(b)(5).

Because all of the standard's other requirements are "tied to" the permissible exposure limit and the dermal contact prohibition, the court set aside the entire standard (App. 33a).

REASONS FOR GRANTING THE PETITION

1. The Occupational Safety and Health Act requires the Secretary of Labor to establish, for toxic substances, standards of occupational exposure that "most adequately assure[], to the extent feasible, on

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cient information to determine that a standard such as the one under review which it can only say might protect some worker from a leukemia risk is reasonably necessary" (App. 20a-21a; footnotes omitted).

the basis of the best available evidence, that *no* employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." 29 U.S.C. 655 (b)(5) (emphasis added). Because of the great difficulty that has been experienced in determining whether most substances that cause cancer are "safe" in any dose, however small, the Secretary has consistently established standards requiring the lowest level of exposure that can be achieved within bounds of economic and technological feasibility. The Secretary has not attempted to establish comparisons between the costs of the regulation and the measurable benefits of reduced exposure to benzene and certain other toxic substances, and he believes that in this case he cannot establish such a comparison. Three courts of appeals have sustained the Secretary's approach. *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974) (asbestos dust); *Society of Plastics* v. *OSHA*, 509 F.2d 1301 (2d Cir.), cert. denied, 421 U.S. 992 (1975) (vinyl chloride); *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825 (3d Cir. 1978), petitions for cert. pending, Nos. 78-918 and 78-919 ("*AISI*") (coke oven emissions). The Secretary is continuing to apply this policy in ongoing administrative proceedings dealing with other carcinogens. See Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk, 42 Fed. Reg. 54148 (1977).

The decision of the court of appeals in the present case holds that this policy is unlawful. According to the court, the Secretary must demonstrate measurable

benefits to be achieved by reductions in exposure to cancer-causing substances. If the relationship between exposure and disease is imperfectly known, so that the benefits cannot be measured, then the Secretary cannot order a reduction in exposure. In reaching this conclusion the court of appeals declined to address the decisions we have mentioned above, stating that they were insufficiently analytical (App. 21a).

The decisions do not simply conflict in result. They employ completely different reasoning. The three earlier decisions recognize the authority of the Secretary, when the evidence establishes no known safe level of exposure to a carcinogen, to resolve doubts in favor of safety. They do not require the Secretary to establish the "savings" attributable to a reduction in exposure; the decision in the present case makes such a computation essential. *AISI* and *Industrial Union*, indeed, explicitly reject the proposition that the statute requires (or even permits) the Secretary to act on the basis of a cost-benefit comparison.[8] They make

[8] The industrial parties in *AISI* argued that the Secretary was required to consider all applicable OSHA standards for a given industry and the cost of each, and then to maximize the number of lives saved (by *all* standards) for a given cost. This test would have required a cost-benefit analysis of every possible regulation and a comparison of the costs and benefits of toxic substances regulation against the costs and benefits of other forms of safety regulation. The court of appeals responded that the role "economic considerations are to play in review of the Secretary's standard" is limited to determining whether the standard is economically feasible, and that means only that the standard will not cause "massive dislocation of industry" or "imperil the existence" of the industry. 577 F.2d at 835-836. See also *Industrial Union*, *supra*, 499 F.2d at 478-481.

it clear that financial considerations may be taken into account only to the extent necessary to demonstrate whether a standard is feasible. The present case thus creates a conflict on a question that potentially affects the conditions of thousands of workplaces and the lives of millions of workers. The decision may well preclude the Secretary from regulating many of the other carcinogens present in the workplace. The question deserves review by this Court.[9]

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[9] The case would deserve review even if it involved only the benzene standard. The regulation governs the occupational exposure of some 629,000 workers to a known cause of cancer (App. 137a). Benzene is a widely-used hydrocarbon, and it can be expected that occupational exposure to it will continue to raise health questions. Although the court of appeals speculated (App. 19a n.23) that scientific evidence soon would permit the Secretary to establish the relationship between exposure to benzene and the incidence of disease, and thus establish the amount of benefits attributable to a reduction in exposure, it offered no sufficient basis for that speculation. The Secretary believes that the court of appeals overestimated the precision available in scientific studies of risk from exposure to carcinogens. There are a number of obstacles that make the measurement of benefits difficult. For example, it is difficult to study the development of cancer in groups of persons because it is not known how much of a given substance they may have been exposed to in the past; moreover, persons may have been exposed to several different causes of cancer, and it is difficult to isolate the effects of each. There may be a substantial lag between initial exposure to a carcinogen and the development of disease; this makes it difficult to know when any sample of persons has developed all of the cases of cancer that may fairly be attributable to a particular substance. In light of these and other difficulties, the Secretary believes that the best studies available now or in the immediate future are not sufficiently precise to permit him to learn the effect of incremental reductions in exposure to benzene of the sort at issue. In other words, the

2. The court of appeals' requirement that the Secretary establish a particular relationship between

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Secretary believes that it is not possible to conclude, with any precision, how many cases of cancer could be avoided by reducing exposure from 10 ppm to five or one ppm. In the absence of such information, it would not be possible to comply with the court of appeals' requirement of detailed cost-benefit analysis.

The court of appeals based its contrary view on three factors. First, the court observed that a physicist representing industry had testified that a "preliminary risk assessment" showed that only two deaths every six years would be averted by the reduction in exposure to one ppm. But the Secretary asked the physicist to supply the basis for this conclusion; although he agreed to do so (Tr. 2752-2753), the Secretary has never received this substantiation. The Secretary discussed and rejected the physicist's unsupported conclusion (App. 161a). Second, the court observed that after the close of the record in this case the EPA released a preliminary report on the relationship between cancer and benzene. See *A Preliminary Report on Population Risk to Ambient Benzene Exposures* (1978). (This report estimates that exposure of the whole population to levels even as low as one part per billion for only 24 hours would cause between 30 and 80 cases of leukemia yearly.) In the Secretary's view this report also does not establish that the relationship between exposure and incidence of leukemia can be constructed with sufficient reliability to be the basis for setting an exposure level under OSHA. The EPA stated (*id.* at 14) that its estimates were devised by "very crude methods" and could be in error by several orders of magnitude, so that it could confidently conclude only that one sort of exposure would cause between 0.3 and 8000 deaths yearly. Such estimates are not sufficiently precise for use in setting occupational health standards. The court's third basis was that the Secretary's consultant on the feasibility of implementing a one ppm standard stated that it could "perform a cost-effectiveness analysis for the benzene standard" (App. 19a n.23). Although one witness so testified, he did not offer to demonstrate how

known benefits and known costs of a toxic substances standard is incorrect. The statute provides that the Secretary must select "the" standard that "most adequately" assures, to the extent feasible, that "no employee" will suffer harm even if he is regularly exposed to the substance "for the period of his working life." 29 U.S.C. 655(b)(5). This provision necessarily precludes a decision to sacrifice health considerations to concerns about cost—at least so long as the cost is "feasible" within the meaning of the section. Nothing in the committee reports on the Act indicates that Congress desired the Secretary to look at the cost of regulation for any purpose other than determining the "feasibility" of a standard. See Senate Committee on Labor and Public Welfare, Legislative History of the Occupational Safety and Health Act of 1970, 92d Cong., 1st Sess. 141-203, 831-892, 1154-1198 (1971) ("Leg. Hist.").

The court of appeals found its cost-benefit requirement in 29 U.S.C. 652(8), which defines a "health

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such a study could be done, or how the data could be acquired. These three factors thus do not support the court of appeals' confident assertion that it is possible soon to learn the relationship between exposure and risk. (There is, of course, no need in this case to consider the utility of risk assessments for other purposes under other statutes. The general subject is under study by an interagency committee that is expected to issue a report in early 1979.)

Moreover, the court also completely overlooked the Secretary's conclusion that the benzene standard is justified by public health considerations without regard to cancer (App. 97a). This error might be sufficient, by itself, to call for reconsideration. We do not press the point further here, however, because the court, by deciding the case with the reasoning it employed, has crippled the Secretary's ability to deal with substances that cause cancer.

standard" as a regulation establishing a practice or rule that is "reasonably necessary or appropriate" to protect health. But the court of appeals cited no legislative history suggesting that this general provision qualifies the Secretary's duty to promulgate the standard that "most adequately" assures that "no" person is harmed by a toxic substance. Section 652(8) requires a standard to be "reasonably necessary or appropriate," but nothing in the statute indicates that a standard is *not* "reasonably necessary or appropriate" in the absence of a particular cost-benefit ratio. The court gave no reason for its apparent conclusion that resolving doubts about safety in favor of lower exposure to carcinogens is not a "reasonably * * * appropriate" means of health protection.

The court of appeals' approach also disregards the structure of the statute. It renders the statutory requirement of "feasibility" in 29 U.S.C. 655(b)(5) redundant. It also overlooks the fact that the Act as a whole indicates a preference for safety "so far as possible." 29 U.S.C. 651. When Congress desired to qualify such a goal with a requirement that costs and benefits be considered, it has done so explicitly.[10] The absence of such a qualification in OSHA

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[10] The Consumer Product Safety Act, for example, contains such a qualification. See 15 U.S.C. 2058(c)(1)(C) and (D). See also S. Rep. No. 92-749, 92d Cong., 2d Sess. 33 (1972). The court of appeals' reliance on cases decided under the Consumer Product Safety Act (see App. 13a-21a) is therefore improper. Where Congress has not precluded an agency from using cost-benefit considerations to develop rules, the agency may properly employ such techniques.

We stress that this case presents the issue whether Section 655(b)(5) prohibits the balancing of costs and benefits for

is thus telling. Cf. *Union Electric Co.* v. *EPA*, 427 U.S. 246 (1976) (structure of Clean Air Act indicates that it contains no requirement that air pollution regulations be economically or technologically feasible); Comment, *Implementing the Anticancer Clauses of the Food, Drug and Cosmetic Act*, 44 U. Chi. L. Rev. 817 (1977) (discussing other statutes regulating carcinogens without respect to cost).

The generally applicable provisions of OSHA all point toward regulation of toxic substances without respect to cost-benefit ratios. In selecting from among competing standards in the first two years of the Act's implementation, the Secretary was required to "pro-

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toxic substances. We do not address balancing in government decisionmaking generally. The technique of balancing costs and benefits is an important decisionmaking tool in government. For example, the President has required that executive branch agencies, including OSHA, perform regulatory analyses for significant regulations, taking into account the full economic consequences of the proposed actions and alternatives. He has also established a regulatory analysis review group to examine the regulatory analysis of significant regulatory proposals of executive branch regulatory agencies, including OSHA. Executive Order 12044, 43 Fed. Reg. 12661 (1978). OSHA itself does not preclude all consideration of cost-benefit assessments in the process of setting health standards for toxic substances. Section 655(b) permits but does not require the Secretary to modify previously-adopted national consensus standards and to issue new standards where none previously existed, although once the Secretary chooses to do so, Section 655(b)(5) requires the Secretary to adopt the standard for toxic substances that is most protective of health, to the extent feasible. In making the determination whether to issue a new standard at all, the Secretary is free to weigh the costs and benefits of the new standards, if it is possible.

mulgate the standard which assures the greatest protection" of the employees. 29 U.S.C. 655(a). And the provision for the regulation of toxic substances is all but inflexible in requiring the Secretary to select "the" standard that "most adequately" ensures that "no" employee is harmed. An employer may obtain variances from these rules, but the grounds for obtaining variances do not include financial considerations. 29 U.S.C. 655(b)(6). See also Leg. Hist. 1188, 1201.

Moreover, the requirement of Section 655(b)(5) that the Secretary act on the basis of the "best available evidence" may preclude cost-benefit considerations. Here, for example, the Secretary found that—as is the case for most carcinogens—the best available evidence does not permit the drawing of conclusions about the number of lives that can be saved by each incremental reduction in exposure. Without such evidence it is impossible to determine the relationship between benefits and costs. But the statute requires the Secretary to act anyway, on what Congress surely knew to be imperfect data. Congress told the Secretary to do the best he could with the "best available" data precisely to prevent the possibility that "the Secretary be paralyzed by debate surrounding diverse medical opinions." Leg. Hist. 848. Congress could not have meant to impose a cost-benefit requirement where, as here, the requirement would produce the very paralysis it sought to avoid.

3. The court of appeals also erred in invalidating the Secretary's prohibition on dermal and eye contact

with liquids containing more than 0.5% benzene. As we have discussed above (see pages 7-8), the medical and scientific evidence was divided about the question whether benzene is absorbed through the skin. The Secretary found that absorption could take place, and the court of appeals acknowledged (App. 25a) that the decision to prohibit dermal contact on this basis is supported by substantial evidence. Under these circumstances, the court's conclusion that the Secretary could not act until another physician had completed another study using radioactive benzene flouts the requirement that the Secretary act on the basis of the best "available" evidence. No radioactive benzene study was "available" at the time of the hearing and, to this date, no one has supplied to the Secretary the results of such a test. No one has argued that the Secretary prevented the parties from performing and submitting such a test. We submit that the Secretary was entitled to act on the basis of the "available" evidence without waiting for the parties to create more.[11]

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[11] If, as some of the industry parties contended and the court of appeals assumed, such a test is uncomplicated and reliable, it is surprising that the industry parties, with so much money at stake, have not engaged physicians to perform the experiment and furnish the results to the Secretary. The Secretary cannot reasonably be blamed for the parties' failure to supply him with relevant evidence. Moreover, if the Secretary were required to wait until the evidence had been supplied—however long that might take—the power to control the timing of new regulations would be effectively transferred from the Secretary to the affected parties, who would have every incentive to delay.

CONCLUSION

The petition for a writ of certiorari should be granted.[12]

Respectfully submitted.

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[12] The Secretary believes that the case should be decided this Term if that is possible. In order to facilitate prompt consideration of the case if the Court should grant review, we are prepared to file a brief on the merits within 21 days after the Court grants the petition for certiorari. We believe that it would be appropriate for the Court to establish a briefing schedule for the other parties that would make the case available for oral argument in April.

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In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY MEMORANDUM FOR PETITIONER

Respondents have argued that, for several reasons, the record of this case does not present the legal questions raised by our petition. We do not discuss this contention with respect to the portions of the regulations dealing with airborne benzene; these points are fully addressed in our petition and the reply brief of the Industrial Union Department, petitioner in No. 78-911. We discuss below the contentions of respondents Rubber Manufacturers Association, *et al.*, concerning the dermal exposure rules. For the reasons we discuss, their interpretation of the record is both erroneous and misleading.

1. Respondents contend that the dermal contact rules cannot be enforced because they were not given adequate notice that the standard would prohibit skin contact with liquids containing more than 0.1% benzene (Rubber Mem. in Opp. 26-30). If they had been given better notice, they say, they would have performed a skin absorption test and supplied the results to the Secretary.

The notice argument presupposes that respondents did not know, until the initiation of the rulemaking, that dermal exposure to benzene would be a subject of regulation. But the statute itself put industry on notice that toxic substances are subject to regulation, and it was common knowledge that benzene is toxic. The central question for industry, then, was not whether the Secretary would begin to investigate exposure to benzene, but how soon he would do so (given the substantial numbers of other toxic substances subject to regulation). Industry could have begun the process of research as soon as the statute was enacted; it did not need to wait until the initial notice of rulemaking. And questions concerning the extent of absorption of benzene into the body through exposed surfaces were obvious candidates for research.

But however this may be, the notice given by the Secretary was more than adequate. The Secretary's initial notice on May 27, 1977, of the proposed standard put respondents on notice that, in and after the second year of regulation, the standard would prohibit dermal and eye contact with liquids containing more than 0.1% benzene; the notice invited comment and evidence on whether exposure to liquids containing *any* benzene should be allowed.[1] The final standard, as amended, is almost

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[1]The original announcement included both a proposed standard and an explanatory statement. The proposed standard stated that "[w]here eye or repeated skin contact with liquid benzene may occur, the employer shall provide and assure that employees wear appropriate protective clothing and equipment to protect the area of the body likely to come in contact with liquid benzene." Section 1910.1028(h), 42 Fed. Reg. 27461 (1977). The proposed standard stated that it did not apply to "work operations where the only exposure to benzene is from liquid mixtures containing 1% (0.1% after one year from the effective date of this standard) or less of benzene by volume, or the vapors released from these liquids." Section 1910.1028(a)(2)(ii), 42 Fed. Reg. 27460 (1977).

The explanatory statement identified 12 issues for discussion at the hearings, including whether the provisions for "personal protective equipment and clothing * * * are appropriate." 42 Fed. Reg. 27452

identical to the originally proposed standard.[2]

Respondents had ample time after May 27 to conduct a study such as Dr. Maibach's. Hearings were held from July 19 through August 10, 1977 (App. 74a). The hearing record was open until September 2, 1977, for the submission of additional evidence. Respondents submitted evidence on the dermal-eye contact issue and percentage exclusion (Rubber Mem. in Opp. 10). Although respondents stated (Rubber Mem. in Opp. 11) that Dr. Maibach's tests could have been performed in six to twelve weeks, respondents did not make any effort to

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(1977). Regarding the question whether the Secretary should allow contact with liquid benzene, the announcement stated (*ibid.*):

> One of the major issues involved in this proceeding is whether the final standard should exempt certain specified operations from its coverage. For the purpose of raising this issue, the proposal, as drafted, does not cover * * * operations in which the only exposure to benzene is from liquid mixtures which contain no more than 0.1% benzene (1% benzene during the first year after the effective date of the standard). The question of whether these types of operations should be exempted is raised herein, and some of the reasons for the suggested exclusion of those operations are set out below. If these operations are excluded from the final standard issued as a result of this rulemaking, they would still be covered by the existing benzene standard in §1910.1000. OSHA seeks public comment and evidence on these issues.

Moreover, the announcement on May 3, 1977, of the Secretary's temporary standard explained that the proceedings on the permanent standard would consider whether any exclusions from a dermal contact ban should be allowed. 42 Fed. Reg. 27470.

[2]The proposal contained an exemption for liquids containing 1% or less benzene during the first year of the standard and 0.1% thereafter. Section 1910.1028(a)(2)(ii), 42 Fed. Reg. 27460 (1977). The original standard—which contained no percentage exclusion—was published on February 10, 1978. In response to claims by industry that the standard was not technologically feasible without a percentage exclusion, the Secretary announced on March 28, 1978, proposed rulemaking to amend the standard to exclude liquids containing 0.1% or less of benzene. 43 Fed. Reg. 12890. The final amended standard exempted liquids with 0.5% or less benzene during the first three years and 0.1% thereafter. Section 1910.1028(a)(2)(iii); App. 252a.

supply such test results during the original proceedings. Other than to claim inadequate notice, respondents offer no excuse for their failure to make such a submission.[3]

2. Respondents contend that "OSHA refused to consider such evidence [whether small amounts of benzene constitute a health hazard] even after the rubber companies expressly warranted to the Agency that Dr. Maibach was conducting a study of issues relating to dermal exposure to benzene" (Rubber Mem. in Opp. 16). This is inaccurate. The hearing during which the Secretary so "refused" was the supplemental hearing to address the question whether the Secretary should allow dermal contact with liquids containing small amounts of benzene (the percentage exclusion issue). By the time this hearing was held the Secretary had concluded that skin or eye contact with benzene is hazardous. He was not required to reopen this determination. At all events, he was not required to grant respondents' request for six months' delay at that stage. Respondents by then had had much more than the 12 weeks they said was needed for a study, but no study had been supplied. Moreover, the agency did not tell respondents that Dr. Maibach's study would not be considered. To the contrary, Grover Wrenn stated, on behalf of the agency, that such a study would be considered. He simply said that the agency would not delay the standard for 26 weeks, as requested, while Dr. Maibach conducted a study (Amend. Tr. 21).[4]

3. Respondents err in contending (Rubber Mem. in Opp. 11 n.18) that only one reference in the administrative record suggests that benzene could be absorbed through the skin. First, Dr. Laigo of the

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[3]Contrary to respondents' assertion (Rubber Mem. in Opp. 28), the court of appeals did not "take cognizance" of any lack of proper notice. The court did not pass on the argument.

[4]"Amend. Tr." refers to the transcript of the proceedings on the amendment to the standard.

National Institute of Occupational Safety and Health testified that benzene "is readily absorbed through the skin" (Tr. 860). Second, the American Conference on Industrial Government Hygienists, and its German counterpart, recommended that dermal contact with liquids containing benzene be avoided because of the potential for absorption through the skin (Exhs. 2-58; 156.2).[5] Third, the fact that benzene is a powerful lipid solvent suggests that it can penetrate the cutaneous barrier (Exh. 2-A-187). Fourth, benzene can damage the skin, and damaged skin is believed to absorb toxic substances more readily than normal skin (Exhs. 2-3 at 25; 2-48; 2-A-111 at 9; 2-A-112 at 2; 2-A-187 at 6.11). Fifth, one study of the Institute of Industrial Toxicology of the Institute of Labor Health, Lodz, Poland, concluded that benzene is absorbed through human skin (Exh. 2-69 at 1), and other studies showed skin absorption in animals (Exh. 2-31 and 2-69).[6] Sixth, Dr. Douglas Smith testified that benzene can be absorbed through the skin (Tr. 860; Rubber Mem. in Opp. 11 n.18). The court of appeals thus properly concluded that the Secretary's finding that benzene is absorbed through the skin is supported by substantial evidence (Pet. App. 25a).

4. Dr. Maibach's preliminary report—supplied for the first time as an appendix to respondents' opposition—actually supports the Secretary's action in two ways.

First, the court of appeals based its holding on the assumption that a short and simple experiment might determine conclusively that benzene is not absorbed through the skin (Pet. App. 22a-27a). Dr. Maibach's

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[5]See 43 Fed. Reg. 5949 (1978).

[6]Because of possible methodological defects in these studies, they were not considered conclusive in themselves. They were, however, viewed as corroborating the experts' opinions that benzene is absorbed.

preliminary study confirms the Secretary's conclusion that benzene is absorbed through the skin.[7]

Second, the attempt to perform a radioactive benzene test illustrates the pitfalls in setting aside a standard based

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imposed by the court of appeals. In light of the fact, however, that skin absorption poses a cancer hazard and the fact that there is no known safe level of absorption, Section 655(b)(5) requires the Secretary, in adopting a rule regarding eye and skin contact, to adopt a standard that most fully protects health, subject only to feasibility.

As to the rate of absorption, the Maibach study is subject to serious question. The study was conducted in a manner that underestimates the absorption rate. First, the subjects were exposed to only a single dose of benzene (Rubber Mem. in Opp. App. 7a), whereas in real life some employees are exposed repeatedly to liquids containing benzene. Dr. Maibach testified in 1977 that the number of doses might well make an important difference (Tr. 2467). Second, much of the dose applied in the Maibach study would have evaporated from the skin, thus reducing the amount of benzene available for penetration. Dr. Maibach testified in 1977 that benzene is very volatile and evaporates rapidly (Tr. 2468). The Maibach subjects were kept outdoors, which would have accelerated evaporation. Third, in the Maibach study liquid benzene was applied to the forearm of a rhesus monkey; the forearms of rhesus monkeys and humans may not be comparable for absorption purposes. Fourth, the rate of absorption through the human skin varies greatly with the part of the body, as Dr. Maibach testified (Tr. 2466, 2480). Studies on absorption through the forearm thus may not indicate the usual rate of absorption. Fifth, the rate of absorption normally increases with the temperature (Tr. 2479). The study does not state the temperature at which the subjects were maintained during the study. Sixth, the Maibach study, which relies on a single application of benzene to the test subjects, does not take into account the fact that repeated contact with benzene can blister the skin and reduce its ability to prevent penetration. In 1977 Dr. Maibach testified that penetration normally is greater through damaged skin than undamaged skin (Tr. 2469). The Maibach study itself admits several of these limitations (Rubber Mem. in Opp. App. 11a).

[7]In light of this, respondents now argue that the rate of absorption is so small that the health benefits of the dermal-eye contact prohibition do not satisfy the separate cost-benefit requirement imposed by the court of appeals. In light of the fact, however, that skin absorption poses a cancer hazard and the fact that there is no known safe level of absorption, 29 U.S.C. 655(b)(5) requires the Secretary, in adopting a rule regarding eye and skin contact, to adopt a standard that most fully protects health, subject only to feasibility.

on speculation that evidence can be created readily. Dr. Maibach testified in the Secretary's hearing not only that his carbon-14 test would determine whether benzene is absorbed through the skin but also that those tests would determine a number of other related issues. The court of appeals was plainly influenced by the prospect that "conclusive" answers to many questions were "readily" available in a short time through a simple study (Pet. App. 26a). The time proved to be not-so-short. Dr. Maibach's "preliminary" results were received by the Secretary one-and-a-half years after Dr. Maibach testified that his study could be completed in six to twelve weeks. The results proved to be not-so-conclusive (see note 7, *supra*). And Dr. Maibach's study did not address any issue except to confirm the Secretary's conclusion that benzene is absorbed through the skin and to suggest that the rate of absorption depends on the amount applied. Dr. Maibach now proposes (Rubber Mem. in Opp. App. 10a) further experiments, and, we assume, further delays to tackle some of the additional issues that the court of appeals thought would be resolved by Dr. Maibach's initial effort (see Pet. App. 26a).

This sequence of events illustrates our point that industry often will be able to point to toxicological research that allegedly will provide conclusive answers to medical uncertainties. It also illustrates the mischief that can be caused when health standards are postponed in hope that "one more study" will resolve all doubt. These considerations underscore Congress' wisdom in requiring the Secretary to consider only "available" evidence in discharging his responsibility to protect the health of employees.[8]

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[8]Of course, if, after the Secretary has promulgated a standard, new evidence comes to light casting doubt on the wisdom of that standard, any interested person may ask the Secretary to make

For these reasons, as well as those discussed in our petition, we respectfully submit that the Court should grant review.

WADE H. MCCREE, JR.
Solicitor General

FEBRUARY 1979

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appropriate revisions in the standard. Our point here is simply that the prospect of additional evidence becoming available does not require the Secretary to defer promulgating the standard in the first place.

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